Attorney Case No.: IVGN 207

#### IN THE LINITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:		Customer No.: 52059
CHU et al.		CERTIFICATE OF E-FILING
Patent No.:	7,166,745 B1	I hereby certify that this paper is being electronically filed using USPTO EFS-Web and is addressed to the Commissioner for Patents. Attn: CERTIFICATE OF CORRECTIONS BRANCH.
Issue Date:	January 23, 2007	P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.
For: Transfection Reagents		
		/Tracy Sauers/ 7/31/09 Date of Deposit

## REQUEST FOR CERTIFICATE OF CORRECTION UNDER 35 U.S.C. 254 and 37 C.F.R. § 1.322

## ATTN: CERTIFICATE OF CORRECTIONS BRANCH

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Patentees request a Certificate of Correction to correct errors set forth in the attached form PTO/SB/44 (Rev. 04/05). The errors are on the part of Patent and Trademark Office.

Corrections to issued Claim 13 (original claim 25), Claim 19 (original claim 31), and Claim 34 (original Claim 51) provide the correct formula structures. The correction to issued Claim 98 (original claim 139) replaces "consisting of alkyl group" with -- consisting of H, an alkyl group --.

Basis for the requested corrections to issued Claims 13, 19, 34, and 98, present in the Issued Patent at Columns 69 and 70, lines 25-43, Column 71, lines 30-43, Column 76, lines 45-60, and Column 92, line 9, respectively, is found in the Responses to Office Actions filed February 25, 2005 and May 20, 2005. The listing of the claims, dated February 25, 2005 (Attachment A), was entered in the Ex Parte Quayle Action mailed on April 27, 2005 (Attachment B) wherein a clean copy of the listing of the claims was requested and provided with "The Response to Office Action", filed May 20, 2005 (Attachment C).

Attorney Case No.: IVGN 207

That "OR<sub>6</sub>" of Claim 34 (original Claim 51) is to be changed to --OR<sub>6</sub>-- is further evident from Claim 34 itself in the "wherein" clause "wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate" and from the structure at the bottom of, and bridging, columns 31 and 32.

Patentees respectfully request correction of the errors.

No fees are believed due for the filing of the present document. However, should any fees be due, The Commissioner for Patents is authorized to charge the fee (\$100) under §1.20(a) to Life Technologies Inc. Deposit Account No. 50-3994. Any deficiency or overpayment should be charged or credited to the deposit account.

Respectfully submitted,

Date: July 31, 2009

Correspondence Address: LIFE TECHNOLOGIES C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402 /Gloria L. Norberg/ Gloria L. Norberg Reg. No.

Gloria L. Norberg Reg. No. 36,706 Agent for Patentee

Page

# UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 7,166,745 B1

APPLICATION NO : 09/438.365

ISSUE DATE : January 23, 2007

INVENTOR(S) : CHU et al.

## It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

### In Columns 69 and 70, lines 25-43, in Claim 13, delete

#### and insert therefor

#### MAILING ADDRESS OF SENDER (Please do not use customer number below):

LIFE TECHNOLOGIES C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402

This collection of information is required by 97 CFR 13/22, 13/23, and 13/24. The information is required to obtain or retain a benefit by the public which is to fill (and by the VESTO to process) an application. Confidentially is governed by 38 U.S. C. 13/24 and 37 CFR 11.4 This collection is entired to take 1.0 hour to complete, including gathering, preparing, and automitting the completed application from to the USPTO. Time with vary depending upon the completed application from to the USPTO. Time with vary depending upon the completed application from the USPTO. Time with vary depending upon the Confidential Confident

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## CERTIFICATE OF CORRECTION

PATENT NO. : **7,166,745 B1** 

APPLICATION NO. : 09/438,365
ISSUE DATE : January 23, 2007
INVENTOR(S) : CHU et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 71, lines 30-43, in Claim 19, delete

and insert therefor

MAILING ADDRESS OF SENDER (Please do not use customer number below):

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## UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE OF CORRECTION

Page 3 of 4

PATENT NO. : 7,166,745 B1

APPLICATION NO. : 09/438,365

ISSUE DATE : January 23, 2007

INVENTOR(S) : CHU et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 76, lines 45-60, in Claim 34, delete

and insert therefor

MAILING ADDRESS OF SENDER (Please do not use customer number below):

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## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

		CERTIFICATE OF CONTINECTION
PATENT NO. APPLICATION NO. ISSUE DATE INVENTOR(S)	: : : : : : : : : : : : : : : : : : : :	Page 4 of 4 7,166,745 B1 09/438,365 January 23, 2007 CHU et al.
It is certified that error below:	арре	ears in the above-identified patent and that said Letters Patent is hereby corrected as shown
In Column 92, line 9 – consisting of H, an		Claim 98, delete "consisting of alkyl group" and insert therefor yl group
MAILING ADDRESS OF	SEN	NDER (Please do not use customer number below):

LIFE TECHNOLOGIES C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Amendments to the Claims:

La Calaina

This listing of claims will replace all prior versions and listing of claims in the application.

## Listing of the claims

## 1-9. (Canceled)

10. (Previously presented) A compound having the formula:

wherein

X<sup>-</sup> is a physiologically acceptable anion; and a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion.

- 11. (Canceled)
- 12. (Currently amended) A compound having the formula:

wherein

X is a physiologically acceptable anion;

a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion;

R<sub>1</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>6</sub>, independently of one another, are selected from the group consisting of H, an alkyl group, an alkenyl group, an alkynyl group, and an aryl group, wherein any one of R<sub>1</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>6</sub> are optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group, and at least two of R<sub>1</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>6</sub>, are straight-chain, branched, or cyclic alkyl, alkynyl, or alkenyl-or-aryl groups having from 8 to about 24 carbon atoms attached to each N and R<sub>1</sub>, R<sub>3</sub>, R<sub>4</sub> and R<sub>6</sub> may optionally be covalently linked with each other:

R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate; and I is an integer from 1 to about 4.

(Previously presented) The compound as claimed in claim 12, which is:

wherein R7 and R8 are independently H or a carbohydrate.

(Previously presented) The compound as claimed in claim 13, wherein R<sub>7</sub> and R<sub>8</sub> are H.

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- 15. (Canceled)
- 16. (Currently amended) A compound having the formula:

$$0 = \begin{pmatrix} (R_2)_{lm} & (R_5)_{ln} & \chi_a \\ \downarrow & \downarrow & \downarrow \\ R_1 & R_4 & \chi_b \end{pmatrix}$$

wherei⊓

R<sub>1</sub>, R<sub>2</sub>, R<sub>4</sub> and R<sub>5</sub> independently of one another, are selected from the group consisting of H, an alkenyl group, an alkynyl group, and an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group, and at least two of R<sub>1</sub>, R<sub>2</sub>, R<sub>4</sub> and R<sub>5</sub> are a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms attached to each N;

Z is selected from the group consisting of spermiyl, spermidlyl, amino acid, peptidyl, diaminoalkyl, and polyamine;

X is a physiologically acceptable anion;

m and n are 0 or 1:

1, b and c are integers independently selected from 1 to about 4; and

a is the number of positive charges in the compound divided by the valence of the anion.

17. (Previously presented) The compound as claimed in claim 16, which is:

18. (Currently amended) The compound as claimed in claim 16, which is:

19. (Currently amended) The compound as claimed in claim 16, which is:

- 20. (Canceled)
- 21. (Currently amended) A compound having the formula:

wherein

Q is N;

X- is a physiologically acceptable anion;

a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion;

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R1 and R4 independently of one another, are selected from the group gendently of one another, consisting of H, -(CH2)o-D-Z, an alkyl group, an alkyl ether group, an alkenyl group, an aryl group, and an alkyl or alkyl ether group substituted by one or more of an alcohol, an aminoalcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, an alkylthio, a urea, a thiourea, a guanidyl, or a carbamoyl group, R1 and R4 may optionally be covalently linked with each other, to form a cyclic moiety; at least one of R1 and R4 is a straight-chain, branched, or cyclic alkyl, alkenyl, or alkynyl or aryl group having from 8 to about 24 carbon atoms:

R<sub>2</sub> and R<sub>5</sub> independently of one another, are selected from the group consisting of H, an alkenyl group, an alkynyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a quanidyl, or a carbamoyl group;

Z is selected from the group consisting of spermiyl, spermidyl, aminoacid, peptidyl, diaminoalkyl, and polyamine;

D is N, O, S, or a bond:

R<sub>7</sub> and R<sub>8</sub> independently are H or a carbohydrate;

m and n are 0-or 1, when m is 1, the Q-bonded to R2 is positively charged and when n is 1 the O bended to Rs is positively charged:

- I is an integer selected from 1 to about 4; and p is an integer from 1 to about 10.
- 22. (Previously presented) The compound as claimed in claim 21 wherein R<sub>7</sub> and R<sub>B</sub> are H.
- 23. (Previously presented) The compound as claimed in claim 21 which is:

- 24. (Previously presented) The compound according to claim 23, wherein  $R_7$  and  $R_8$  are H.
- 25. (Currently amended) The compound according to claim 21, which is

## wherein R7 and R8 independently are H or a carbohydrate.

- 26. (Previously presented) The compound as claimed in claim 25, wherein  $R_7$  and  $R_8\, {\rm are}\, H.$
- 27. (Currently amended) The compound as claimed in claim 21, which is

wherein R7 and R8 independently are H or a carbohydrate.

- 28. (Previously presented)The compound as claimed in claim 27, wherein  $R_7$  and  $R_9$  are H.
- 29. (Previously presented) A compound having the formula:

wherein each of  $R_1$  and  $R_4$  is a -(CH<sub>2</sub>)<sub>8</sub>-CH=CH-(CH<sub>2</sub>)<sub>7</sub>-CH<sub>3</sub> group; and I, b, and c are integers independently selected from 1 to about 4.

30. (Previously presented) The compound as claimed in claim 29, which is:

31. (Previously presented) The compound as claimed in claim 29, which is:

32. (Currently amended) A compound having the formula:

$$H_2N$$
 $N$ 
 $CH_2$ 
 $R_4$ 
 $R_4$ 
 $R_8$ 

wherein

each of R<sub>1</sub> and R<sub>4</sub> is a straight-chain, branched, or cyclic alkenyl, <u>or</u> alkynyl, <u>or anyl</u> group having from about 8 to about 24 carbon atoms;
R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate; and
I is an integer Independently selected from 1 to 4.

33. (Previously presented) The compound as claimed in claim 32, which is:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

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- 34. (Previously presented) The compound as claimed in claim 33, wherein  $R_{\text{mu}}$ , and  $R_{\text{a}}$  are H.
- 35. (Previously presented) The compound as claimed in claim 32, which is:

wherein R7 and R8 are independently H or a carbohydrate.

- 36. (Previously presented) The compound as claimed in claim 35, wherein  $R_7$  and  $R_8$  are H.
- 37. (Canceled)
- 38. (Previously presented) A compound having the formula:

wherein

lie 4

R<sub>1</sub> and R<sub>4</sub> are straight-chain alkyl groups having 14 or 16 ஓற்ற ஆண்டில் வில்லியில் இருவர். and

R<sub>7</sub> and R<sub>8</sub> are independently selected from H or a carbohydrate.

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- 39. (Canceled)
- 40. (Previously presented) The compound as claimed in claim 38, wherein  $R_7$  and  $R_9$  are both H.
- 41. (Currently amended) A compound having the formula:

wherein

Z is selected from the group consisting of amine, spermiyl, carboxyspermiyl, guanldyl, spermidinyl, putricinyl, diaminoalkyl, pyridyl, piperidinyl, pyrrolidinyl, polyamine, amino acid, peptide and protein;

- D is Q or a bond;
- p is an integer from 1 to about 10;

 $R_1$  and  $R_4$ , independently of one another, are selected from the group consisting of H,  $-(CH_2)_p$ –D-Z, an alkyl group, an alkenyl group, an aryl group, an alkynyl group, and an alkyl ether group wherein any one of  $R_1$  and  $R_4$  are optionally substituted by one or more of an alcohol, an aminoalcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, an alkylthio, a urea, a thiourea, a guanidyl, or a carbamoyl group,  $R_1$ , and  $R_4$  may optionally be covalently linked with each other to form a cyclic moiety; and at least one of

 $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from 8 to about 24 carbon atoms; and

consisting of H, an alkenyl group, an alkynyl group, an aryl group and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amilde, ு an ether, a polyether, a polyamide; an ester, a mercaptan, a urea, a thiourea, a guanidyl and a carbamoyl group;

R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate;

X<sup>-</sup> is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion:

m and n are 0 or 1;

i and j are integers selected from 2 to about 3; and k is an integer selected from 1 to about 3.

- 42. (Canceled)
- 43. (Previously presented) A compound having the formula:

44. (Previously presented) A compound having the formula:

- 45. (Canceled)
- 46. (Currently amended) A compound having the formula:

## wherein

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

R₂ and R₃, independently of one another, are selected from the group consisting of a, an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thlourea, a guanidyl, or a carbamoyl group;

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X- is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the

valence of the anion; ' and a more than anion;

m and n are 0 or 1, when m is 1, the N bonded to R2 is positively charged

and when n is 1, the N bonded to Rs is positively charged;

i and I are integers selected from about 2 to about 3; and

k is an integer selected from 1 to about 3.

47. (Currently amended). The compound as claimed in claim 46, which is:

- 48. (Canceled)
- 49. (Currently amended) A compound having the formula:

wherein

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

 $R_2$  and  $R_5$ , independently of one another, are selected from the group consisting of an alkenyl group, an aryl group, and an alkyl group optionally

substituted by one or more of an alcohol, an amine, an amide, an ether,  $a_{16} = \max_{0 \le n \le n \le 1} \max_{0 \le n \le 1$ 

m and n are-0-or 1;

i and j are integers from about 2 to about 3;

k is an integer from 1 to about 3;

 $L_1$  and  $L_2$ , independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of CH2, O, S and NH.

50. (Currently amended) The compound as claimed in claim-49, which is:

51. (Previously presented) A compound having the formula:

3 E

wherein R7 and R8 are independently H or a carbohydrate.

- 52. (Previously presented) The compound as claimed in claim 51, wherein  $R_7$  and  $R_8$  are H.
- 53. (Previously presented) A compound having the formula:

54. (Previously presented) A compound having the formula:

wherein

X- is a physiologically acceptable anion; and

a is the number of positive charges in the compound divided by the valence of the anion.

55. (Currently amended) A compound having the formula:

wherein

Q is N:

X is a physiologically acceptable anion;

a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion;

R<sub>1</sub> and R<sub>4</sub> independently of one another, are selected from the group consisting of H, –(CH<sub>2</sub>)<sub>p</sub>–D-Z, an alkyl group, an alkyl ether group, an alkenyl group, an aryl group, and an alkyl or alkyl ether group substituted by one or more

of an alcohôl, art aminoalcohol, an amine, an amide, an ether, a polyether, a anonor enter in the polyamide, an ester, a mercaptan, an alkylthio, a urea, a thiourea, a guanidyl, or carciants and the acarbamoyl group, R<sub>1</sub> and R<sub>4</sub> may optionally be covalently linked with each other, to form a cyclic moiety; and at least one of R<sub>1</sub> and R<sub>4</sub> is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from 8 to about 24.....

R<sub>2</sub> and R<sub>5</sub>, independently of one another, are selected from the group consisting of H, an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercapten, a urea, a thiourea, a guanidyl, or a carbamoyl group;

Z is selected from the group consisting of amine, spermlyl, spermidyl, carboxyspermlyl, guanidyl, spermidinyl, putricinyl, pyridyl, piperidinyl, pyrrollidinyl, aminoacid, peptidyl, diaminoalkyl, and polyamine;

D is N. O. S. or a bond;

i and j are integers from about 2 to about 3;

k is an integer from 1 to about 3;

m, n, r and u are 0 or 1;

p is an integer from 1 to about 10;

 $\mathsf{L}_1$  and  $\mathsf{L}_2$  , independently from one another, are an alkylene or an alkylene ether, and

Y is selected from the group consisting of CH2, O, S and NH.

56. (Currently amended) [[A]] <u>The</u> compound <u>as claimed in claim 55</u> having the formula:

#### wherein

X- is a physiologically acceptable anion;

\_\_\_\_\_a is the number of positive charges in the compound divided by the valence of the anion;

R<sub>1</sub> and R<sub>4</sub>, independently of one another, are straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl groups having from about 8 to about 24 carbon atoms [[;]]

R<sub>2</sub> and R<sub>6</sub>, independently of one another, are selected from the group consisting of H<sub>1</sub>, an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an armine, an amide, an ether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group;

m and n are 0 or 1:

i and i are integers from about 2 to about-3;

k-is an integer from 1-to about 3:

L; and L; independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of CH2, O, S and NH.

57. (Previously presented) A compound having the formula:

58. (Previously presented) A compound having the formula:

wherein R7 and R8 are independently H or a carbohydrate.

- 59. (Previously presented) The compound as claimed in claim 58, wherein  $R_7$  and  $R_8$  are H.
- 60. (Previously presented) A compound having the formula:

61. (Previously presented) A compound having the formula:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 62. (Previously presented) The compound as claimed in claim 61, wherein  $R_7$  and  $R_8$  are H.
- 63. (Canceled)
- 64. (Currently amended) A compound having the formula:

$$N = L_1 - N^{\frac{1}{2}} - \left\{ (CH_2)_1 - Y - (CH_2) \right\}_{k} - N^{\frac{1}{2}} - L_2 - N$$

$$R_2 = \frac{1}{2} - \frac{1}{2$$

wherein

X is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion;

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

R<sub>2</sub> and R<sub>5</sub>, independently of one another, are selected from the group consisting of an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamovl group;

m and n are 0 or 1:

i and i are integers from about 2 to about 3:

k is an integer from 1 to about 3;

 $L_1$  and  $L_2$ , independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of CH2, O, S and NH.

65. (Currently amended) The compound as claimed in claim 64, which is:

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66. (Previously presented) A compound having the formula:

wherein R7 and R8 are independently H or a carbohydrate.

67. (Previously presented) The compound as claimed in claim 66, wherein  $R_7$  and  $R_8$  are H.

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68. (Previously presented) A compound having the formula:

wherein R7 and R8 are independently H or a carbohydrate.

- 69. (Previously presented) The compound as claimed in claim 68, wherein  $R_7$  and  $R_9$  are H.
- 70. (Canceled)
- 71. (Currently amended) A compound having the formula:

wherein

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

R<sub>2</sub> and R<sub>5</sub>, independently of one another, are selected from the group consisting of an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or, say, a r.e. carbane, a carbamoyl group;

m and n are-0 or 1;

i and j are integers from about 2 to about 3;

k is an integer from 1 to about 3;

 $\ensuremath{L_1}$  and  $\ensuremath{L_2}$  independently from one another, are an alkylene or an alkylene ether, and

Y is selected from the group consisting of CH2, O, S and NH.

72. (Currently amended) The compound as claimed in claim 71, which is:

73. (Previously presented) A compound having the formula:

wherein  $R_7$  and  $R_8$  are independently H or a carbohydrate.

- 74. (Previously presented) The compound according to claim 73, wherein  $R_7$  and  $R_8$  are H.
- 75. (Previously presented) A compound having the formula:

wherein R7 and R8 independently are H or a carbohydrate.

76. (Previously presented) The compound as claimed in claim 75, wherein R<sub>Repter 中央方面,我们在</sub> and R<sub>B</sub> are H.

(Canceled)

78. (Currently amended) A compound having the formula:

#### wherein

X- is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion;

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

R₂ and R₃ independently of one another, are selected from the group consisting of an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamovl group:

m and n are 0 or 1:

i and i are integers from about 2 to about 3;

k is an integer from 1 to about 3;

 $\ensuremath{L_1}$  and  $\ensuremath{L_2},$  independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of CH2, O, S and NH.

79. (Previously presented) A compound having the formula:

t troy :

80. (Previously presented) A compound having the formula:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

81. (Previously presented) The compound as claimed in claim 80, wherein  $R_7$  and  $R_8$  are H.

82. (Previously presented) A compound having the formula:

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wherein R7 and R8 are Independently H or a carbohydrate.

- 83. (Previously presented) The compound as claimed In claim 82, wherein  $R_7$  and  $R_8$  are H.
- 84. (Previously presented) A compound having the formula:

85. (Currently amended) A compound having the formula:

wherein

X- is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion;

Y is selected from the group consisting of  $CH_2$ , an ether, a polyether, an  $\frac{1}{2}$   $\frac{1}{2}$   $\frac{1}{2}$  amide, a polyamide, an ester, a sulfide, a urea, a thiourea, a guanidyl, a carbonate, a phosphate, a sulfate, a sulfoxide, an imine, a carbonyl, and a secondary amino group and wherein Y is optionally substituted by  $-X_1-L' -X_2-Z$  or -Z';

 $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_9$ , independently of one another, are selected from the group consisting of H,  $-(CH_2)_F$ -D-Z, an alkyl group, an alkenyl group, an aryl group, an alkynyl group, and an alkyl ether group wherein any one of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  are optionally substituted by one or more of an alcohol, an aminoalcohol, an amine, an ether, a polyether, a polyamide, an ester, a mercaptan, an alkylthio, a urea, a thiourea, a guanidyl, or a carbamoyl group, and at least one of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from 6 to about 64 carbon atoms; and  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  may optionally be covalently linked with each other or with Y, to form a cyclic moiety;

Z is selected from the group consisting of amine, spermiyl, carboxyspermiyl, guanidyl, spermidinyl, putricinyl, diaminoalkyl, pyridyl, piperidinyl, pyrrolidinyl, polyamine, amino acid, peptide, and protein;

 $X_1$  and  $X_2$ , independently of one another, are selected from the group consisting of NH, O, S, alkylene, and arylene;

L' is selected from the group consisting of alkylene, alkenylene, alkynylene, arylene, alkylene ether, and polyether;

D is O, S, or a bond;

m and n are-0 or 1; and

i, j, k, i and p are integers from 1 to about 10.

86. (Previously presented) The compound as claimed in claim 85, wherein at least one of R₁ and R₄ is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms.

- 87. (Previously presented) The compound as claimed in claim 85, wherein the alkyl ether optionally substituted by one or more alcohol groups is a carbohydrate.
- 88. (Previously presented) The compound as claimed in claim 87, wherein the carbohydrate is selected from the group consisting of galactose, fructose, glucose, maltose, sucrose, cellobiose, lactose, mannose, glucopyranose, mannopyranose and galactopyranose.
- 89. (Previously presented) The compound as claimed in claim 85, wherein Y is selected from the group consisting of CH<sub>2</sub>, an ether, a polyether, an amide, a polyamide, an ester, a sulfide, a urea, a thiourea, a guanidyl, a carbamoyl, a carbonate, and a secondary amino group.
- 90. (Previously presented) The compound as claimed in claim 89, wherein at least one of R<sub>1</sub> and R<sub>4</sub> is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms.
- (Previously presented) The compound as claimed in claim 89, wherein the alkyl ether optionally substituted by one or more alcohol groups is a carbohydrate.
- 92. (Previously presented) The compound as claimed in claim 91, wherein the carbohydrate is selected from the group consisting of galactose, fructose, glucose, maltose, sucrose, cellobiose, lactose, mannose, glucopyranose, mannopyranose and galactopyranose.
- 93-100. (Canceled)

- 102. (Currently amended) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 89 and 414 or 138 and at least one additional component selected from the group consisting of a cell, cells, a cell culture, a cell culture media, a neutral lipid, a nucleic acid, and a transfection enhancer.
- 103. (Canceled)
- 104. (Currently amended) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, <u>29</u>, 32, <u>33, 35, 38, 41, 46, 49, 55, 56, 64, 71, <del>75, 78, 85, 89 and 111</del> or 138.</u>
- 105. (Canceled)
- 106. (Canceled)
- 107. (Currently amended) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 66, 64, 71, 75, 78, 85, 89 and 111 or 138 and at least one additional component selected from the group consisting of a cell, cells, a cell culture medium, a nucleic acid, a transfection, enhancer and instructions for transfecting a cell or cells.
- 108. (Currently amended) A method for introducing a polyanion into a cell or cells, said method comprising forming a lipid aggregate from a positively charged compound of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 89 and 111 or 138, contacting the lipid aggregate with a

polyamon to form a positively-charged polyamon-lipid aggregate complex and ക്ഷ്യപ്പിലെ ക്രാവിഷ്ടന incubating the complex with a cell or cells.

109. (Currently amended) A method for introducing a biologically active substance into a cell, said method comprising forming a lipid aggregate of a compound of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 89 and 111 or 138 and a biologically active substance and incubating the lipid aggregate with a cell or cell culture.

#### 110. (Canceled)

111. (Previously presented) A compound which is:

 $N^1,N^4$ -dipalmitolyl- $N^1,N^4$ -di-[2-hydroxy-3-(N-amInopropyl)]-diaminobutane;  $N^1,N^4$ -distearyl- $N^1,N^4$ -di-[2-hydroxy-3-(N-aminopropyl)]-diaminobutane;  $N^1,N^4$ -diiauryl- $N^1,N^4$ -di-[2-hydroxy-3-(N-aminopropyl)]-diaminobutane;  $N^1,N^2$ -diiauryl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-diaminoethane;  $N^1,N^2$ -dipalmitolyl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-diaminoethane;  $N^1,N^2$ -dipalmitolyl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-diaminoethane;  $N^1,N^2$ -distearyl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-diaminoethane;  $N^1,N^2$ -diamyl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine;  $N^1,N^2$ -dipalmitolyl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine;  $N^1,N^2$ -dipalmitolyl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine;  $N^1,N^2$ -distearyl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine;  $N^1,N^2$ -dilauryl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine;  $N^1,N^2$ -dilauryl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine;  $N^1,N^2$ -dilauryl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine;  $N^1,N^2$ -dilauryl- $N^1,N^2$ -di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine;

N<sup>1</sup>,N<sup>4</sup>-dimyristyl-N<sup>1</sup>,N<sup>4</sup>-dl-[2-hydroxy-3-(N-sperminecarboxamido)aminopropyl[-diaminobutane;

 $N^1,N^4$ -dipalmityl- $N^1,N^4$ -di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-dlamlnobutane;

- $\label{eq:continuous} {}_{n,n}^{1},N^{4}\text{-dipalmitolyl-}N^{1},N^{4}\text{-di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-diaminobutane;}$
- $N^1,N^4$ -distearyl- $N^1,N^4$ -di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-diaminobutane;
- $N^1,N^4$ -dilauryl- $N^1,N^4$ -di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-diaminobutane;
- N<sup>1</sup>,N<sup>8</sup>-dimyrlstyl-N<sup>1</sup>,N<sup>8</sup>-di-[2-hydroxy-3-(N-sperminecarboxamido)aminopropyl]-Jeffamine;
- N<sup>1</sup>,N<sup>8</sup>-dipalmityl-N<sup>1</sup>,N<sup>8</sup>-di-[2-hydroxy-3-(N-sperminecarboxamido)aminopropyll-Jeffamine:
- $N^1,N^8$ -dipalmitolyl- $N^1,N^8$ -dl-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-Jeffamine;
- $N^1,N^8$ -distearyl- $N^1,N^8$ -di-[2-hydroxy-3-(N-sperminecarboxamldo)-aminopropyl-Jeffamine:
- $N^1,N^\theta$ -dilauryl- $N^1,N^\theta$ -di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-Jeffamine;
- $N^1.N^8$ -dioleyi- $N^1.N^8$ -di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyi]-Jeffamine;
- $N^1,N^2$ -dimyristyl- $N^1,N^2$ -di- $\{2$ -hydroxy-3-(N-sperminecarboxamido)- aminopropy[-diarninoethane;
  - $N^1,N^2$ -dipalmityl- $N^1,N^2$ -di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-diaminoethane;
  - N<sup>1</sup>,N<sup>2</sup>-dipalmitolyl-N<sup>1</sup>,N<sup>2</sup>-di-[2-hydroxy-3-(N-sperminecarboxamido)aminopropy[]-diaminoethane;
  - N<sup>1</sup>,N<sup>2</sup>-distearyl-N<sup>1</sup>,N<sup>2</sup>-di-[2-hydroxy-3-(N-sperminecarboxamido)aminopropyl]-dlaminoethane; or
- $N^1$ ,  $N^2$ -dilauryl- $N^1$ ,  $N^2$ -di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-diaminoethane.
- 112. (Previously presented) A compound which is:

## 113.-116. (Canceled)

- 117. (Currently amended) A composition comprising one or more compounds of any one of claims 12, 16, 21, <u>29</u>, 32, <u>33</u>, 35, 38, 41, 46, 49, 55, <del>56</del>, 64, 71, <del>75</del>, 78, 85, <del>89 and 111</del> or <u>138</u> and at least one additional lipid aggregating compound.
- 118. (Currently amended) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 89 and 411 or 138 and at least one additional lipid aggregating compound, where the additional lipid aggregating forming compound is selected from at least one of DOPE, DOPC or cholesterol.
- 119. (Currently amended) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 89 and 111 or 138 and at least one neutral lipid or at least one other cationic lipid.

- 120. (Currently amended) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 89 and 111 or 138 and at least one cationic lipid, where the cationic lipid is-selected from the group consisting of DOSPA, DOTMA, DMRIE, DOTAP, DOGS and TM-TPS
- "" "斯"·斯 义:

- 121. (Currently amended) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 76, 78, 85, 89 and 111 or 138.
- 122. (Currently amended) A kit comprising one or more compounds of any one of claims 1 claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 89 and 414 or 138 and at least one additional lipid aggregating forming compound.
- 123. (Currently amended) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, -75, 78, 85, -89 and -111 or 138 and at least one additional lipid aggregating forming compound; where the additional lipid aggregating forming compound is selected from at least one of DOPE, DOPC or cholesterol.
- 124. (Currently amended) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 49 and 111 or 138 and at least one neutral lipid or at least one other cationic lipid.
- 125. (Currently amended) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85,89 and 111 or 138 and at least one other cationic lipid, where the cationic lipid is selected from the group consisting of DOSPA, DOTMA, DMRIE, DOTAP, DOGS and TM-TPS.

- 126. (Currently presented) A lipid aggregate comprising one or more (Currently presented) A lipid aggregate comprising one or more 56, 64, 71, 75, 78, 85, 89 and 111 or 138 and at least one additional lipid Wes 35 aggregating forming compound.
- 127. (Currently amended) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71,-75, 78, 85, 89 and 111 or 138 and at least one additional lipid aggregating forming compound, where the additional lipid aggregating forming compound is selected from at least one of DOPE, DOPC or cholesterol.
- 128. (Currently amended) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 56, 64, 71, 75, 78, 85, 89 and 111 or 138 and at least one neutral lipid or at least one other cationic lipid.
- 129. (Currently amended) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55. 56, 64, 71, 75, 78, 85, 89 and 111 or 138 and at least one other cationic lipid selected from the group consisting of DOSPA, DOTMA, DMRIE, DOTAP, DOGS and TM-TPS.
- 130. Canceled
- 131. Canceled
- 132. Canceled
- 133. (Currently amended) A kit comprising-the a lipid aggregate of claim 128 comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33,

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35, 38, 41, 46, 49, 55, 64, 71, 78, 85, and 138 and at least one neutral lipid or at least one other cationic lipid.

#### . 134. Canceled

135. (Currently amended) The compound of claim 12 wherein  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H, and an alkyl group and at least two of  $R_1$ ,  $R_2$ ,  $R_4$ , and  $R_6$ , are straight-chain alkyl groups having from 8 to about 24 carbon atoms attached to each N.

136. (Currently amended) The compound of claim 135 wherein at least two of R<sub>1</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>6</sub>, are straight-chain alkyl groups having-from 14 or 16 carbon atoms attached to each N.

# 137. (Canceled)

138. (New) A compound having the formula:

where:

Q is N:

L is a bivalent organic radical covalently linking each Q:

r, s, u and v are1;

X is a physiologically acceptable anion;

a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion;

 $R_1,\,R_3,\,R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H, an alkyl group, an alkenyl group, an alkynyl group, and an

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aryl group, wherein any one of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  are optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, as  $\sim 20\%$  polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group, and at least two of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , are straight-chain, branched, or cyclic alkyl, alkynyl, or alkenyl groups having from 8 to 24 carbon atoms attached to each N and  $R_1$ ,  $R_3$ ,  $R_4$  and  $R_6$  are optionally covalently linked with each other, and

R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 139. (New) The compound of claim 138 wherein  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H, an alkyl group, an alkenyl group, or an alkynyl group.
- 140. (New) The compound of claim 138 wherein  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H, and an alkyl group.
- 141. (New) The compound of claim 138 wherein R7 and R8 are H.
- 142 (New) The compound of claim 138 wherein two of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  are alkyl groups having 14 or 16 carbons.



# United States Patent and Trademark Office

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APPLICATION NO.	APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/438,365	11/12/1999		Yongliang Chu		61-03	9217	
23713	7590	04/27/2005			EXAM	INER	
GREENLEE WINNER AND SULLIVAN P C 4875 PEARL EAST CIRCLE					DAVIS, BRIAN J		
SUITE 200	LASIC	IKCLE -			ART UNIT	PAPER NUMBER	
BOULDER,	CO 803	01			1621		

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.	Applicant(s)	
09/438,365	CHU ET AL.	
Examiner	Art Unit	
Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

# A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM

- THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
- after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

  If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1,704(b).

Status
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4712	Decreesiye to	communication(s)	filed on	2/25/05	/DCE

- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) is/are allowed.
- 6) ☐ Claim(s) is/are rejected.
- 7) Claim(s) See Continuation Sheet is/are objected to.
- 8) Claim(s) are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 12 November 1999 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The path or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    - Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No.
    - 3. Copies of the certified copies of the priority documents have been received in this National Stage
    - application from the International Bureau (PCT Rule 17.2(a)).
    - \* See the attached detailed Office action for a list of the certified copies not received.

# Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
  - Paper No(s)/Mail Date various (6).

- Interview Summary (PTO-413)
   Paper No(s)/Mail Date.
- 5) Notice of Informal Patent Application (PTO-152)
  - 6) Other: \_\_

Continuation of Disposition of Claims: Claims pending in the application are 10,12-14,16-19,21-36,38,40,41,43,44,46,47,49-62,64-69,71-76,78-92,101,102,104,107-109,111,112,117-129,133,135,136 and 138-142.

Continuation of Disposition of Claims: Claims objected to are 10,12-14,16-19,21-36,38,40,41,43,44,46,47,49-62,64-69,71-76,78-92,101,102,104,107-109,111,112,117-129,133,135,136 and 138-142.

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## DETAILED ACTION

#### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/05 has been entered.

#### Information Disclosure Statement

Due to the lengthy prosecution history and the unusually number of documents of record in the application, applicant's assistance is respectfully requested in determining if all submitted IDS forms have been initialed and returned. (Attached to this Office Action are 6 initialed forms.)

# Claim Objections

Claims 10,12-14,16-19,21-36,38,40,41,43,44,46,47,49-62,64-69,71-76,78-92,101,102,104,107-109,111,112,117-129,133,135,136 and 138-142 (all pending claims) are objected to because of the following informalities: due to errors related to the transmission of applicant's FAXed amendment, the amendment is illegible in many, many instances. This is particularly true with regard to subscripted numbers and

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Art Unit: 1621

variables. The examiner respectfully suggests that if amendments are FAXED which include subscripts, written formulas, etc. that the point and typeface be selected appropriately, such that transmission errors do not interfere with legibility. Appropriate correction is required.

Claim 16 is additionally objected to because in the third line from the bottom, the numeral "1" should be deleted and the letter "I" inserted. This is in keeping with the diagram.

Claim 41 is also additionally objected to because in the phrase "D is Q or a bond" should be deleted and the phrase "D is O or a bond" inserted. (This is perhaps merely and instance of the illegibility mentioned above.)

Applicant's assistance is respectfully requested in correcting any other minor errors that may be present in the claims.

# Clarification/Disposition

All rejections have been overcome or withdrawn for reasons of record.

# Allowable Subject Matter

Claims 10,12-14,16-19,21-36,38,40,41,43,44,46,47,49-62,64-69,71-76,78-92,101,102,104,107-109,111,112,117-129,133,135,136 and 138-142 would be allowable once the objections outlined above have been overcome.

Art Unit: 1621

#### Conclusion

This application is in condition for allowance except for the following formal matters: the objections outlined above.

Prosecution on the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO**MONTHS from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1621

BRIAN DAVIS PRIMARY EXAMINER

Brian J. Davis April 25, 2005



# 5-23-05

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

: 09/438.365

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Applicant:

: Chu et al.

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: Davis, Brian J.

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## RESPONSE TO OFFICE ACTION

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This amendment is submitted in response to the ex Parte Quayle Action mailed April 27, 2005.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 41 of this paper.

A legible copy of the amendment filed in this case on February 25, 2005 is submitted herewith as Appendix A.

A copy of an Information Disclosure Statement filed March 9, 2000 along with 5 pages of 1449 forms listing 51 references. A copy of the post card receipt date stamped by the U.S. Patent Office indicating receipt of the IDS and copies of the references submitted.

# Amendments to the Claims:

This listing of claims will replace all prior versions and listing of claims in the application.

# Listing of the claims

- 1-9. (Canceled)
- 10. (Previously presented) A compound having the formula:

## wherein

X<sup>-</sup> is a physiologically acceptable anion; and a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion.

# 11. (Canceled)

# 12. (Previously presented) A compound having the formula:

## wherein

X is a physiologically acceptable anion;

a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion;

 $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H, an alkyl group, an alkenyl group, an alkynyl group, and an aryl group, wherein any one of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  are optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group, and at least two of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , are straight-chain, branched, or cyclic alkyl, alkynyl, or alkenyl or aryl groups having from 8 to 24 carbon atoms attached to each N and  $R_1$ ,  $R_3$ ,  $R_4$  and  $R_6$  may optionally be covalently linked with each other:

R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate; and I is an integer from 1 to about 4.

13. (Previously presented) The compound as claimed in claim 12, which is:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 14. (Previously presented) The compound as claimed in claim 13, wherein  $R_7$  and  $R_8$  are H.
- 15. (Canceled)
- 16. (Currently amended) A compound having the formula:

wherein

 $R_1$ ,  $R_2$ ,  $R_4$  and  $R_5$ , independently of one another, are selected from the group consisting of H, an alkenyl group, an alkynyl group, and an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group, and at least two of  $R_1$ ,  $R_2$ ,  $R_4$  and  $R_5$  are a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms attached to each N:

Z is selected from the group consisting of spermiyl, spermidiyl, amino acid, peptidyl, diaminoalkyl, and polyamine;

X<sup>-</sup> is a physiologically acceptable anion;

m and n are1:

- 4 <u>I</u>, b and c are integers independently selected from 1 to about 4; and a is the number of positive charges in the compound divided by the valence of the anion.
- 17. (Previously presented)The compound as claimed in claim 16, which is:

18. (Previously presented) The compound which is:

19. (Previously presented) The compound which is:

H<sub>2</sub>N

- 20. (Canceled)
- 21. (Previously presented) A compound having the formula:

wherein

Q is N;

X is a physiologically acceptable anion;

a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion;

 $R_1$  and  $R_4$  independently of one another, are selected from the group consisting of H,  $-(\text{CH}_2)_p\text{-}D\text{-}Z$ , an alkyl group, an alkyl ether group, an alkenyl group, an aryl group, and an alkyl or alkyl ether group substituted by one or more of an alcohol, an aminoalcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, an alkylthio, a urea, a thiourea, a guanidyl, or a carbamoyl group,  $R_1$  and  $R_4$  may optionally be covalently linked with each other, to form a cyclic moiety; at least one of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkyl, alkenyl, or alkynyl group having from 8 to 24 carbon atoms:

 $R_2$  and  $R_5$ , independently of one another, are selected from the group consisting of H, an alkenyl group, an alkynyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group;

Z is selected from the group consisting of spermiyl, spermidyl, aminoacid, peptidyl, diaminoalkyl, and polyamine;

D is N. O. S. or a bond:

R<sub>7</sub> and R<sub>8</sub> independently are H or a carbohydrate;

m and n are1:

I is an integer selected from 1 to about 4; and p is an integer from 1 to about 10.

- 22. (Previously presented) The compound as claimed in claim 21 wherein  $R_7$  and  $R_8$  are H.
- 23. (Previously presented) The compound as claimed in claim 21 which is:

24. (Previously presented) The compound according to claim 23, wherein  $R_7$  and  $R_8$  are H.

25. (Previously presented) The compound which is

wherein R<sub>7</sub> and R<sub>8</sub> independently are H or a carbohydrate.

- 26. (Previously presented) The compound as claimed in claim 25, wherein  $R_7$  and  $R_8\, \mbox{are H}.$
- 27. (Previously presented) The compound which is

wherein R<sub>7</sub> and R<sub>8</sub> independently are H or a carbohydrate.

28. (Previously presented)The compound as claimed in claim 27, wherein  $R_7$  and  $R_8$  are H.

29. (Previously presented) A compound having the formula:

wherein each of  $R_1$  and  $R_4$  is a -(CH<sub>2</sub>)<sub>8</sub>-CH=CH-(CH<sub>2</sub>)<sub>7</sub>-CH<sub>3</sub> group; and I, b, and c are integers independently selected from 1 to about 4.

30. (Previously presented) The compound as claimed in claim 29, which is:

31. (Previously presented) The compound as claimed in claim 29, which is:

32. (Previously presented) A compound having the formula:

wherein

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, or alkynyl group having 8 to 24 carbon atoms;

R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate; and I is an integer independently selected from 1 to 4.

33. (Previously presented) The compound as claimed in claim 32, which is:

wherein R7 and R8 are independently H or a carbohydrate.

- 34. (Previously presented) The compound as claimed in claim 33, wherein  $R_7$  and  $R_8$  are H.
- 35. (Previously presented) The compound as claimed in claim 32, which is:

wherein R7 and R8 are independently H or a carbohydrate.

- 36. (Previously presented) The compound as claimed in claim 35, wherein  $R_7$  and  $R_8$  are H.
- 37. (Canceled)
- 38. (Previously presented) A compound having the formula:

## wherein

I is 4,

 $R_{\rm 1}$  and  $R_{\rm 4}$  are straight-chain alkyl groups having 14 or 16 carbon atoms, and

R<sub>7</sub> and R<sub>8</sub> are independently selected from H or a carbohydrate.

- 39. (Canceled)
- 40. (Previously presented) The compound as claimed in claim 38, wherein  $R_7$  and  $R_8$  are both H.
- 41. (Currently amended) A compound having the formula:

## wherein

Z is selected from the group consisting of amine, spermiyl, carboxyspermiyl, guanidyl, spermidinyl, putricinyl, diaminoalkyl, pyridyl, piperidinyl, pyrrolidinyl, polyamine, amino acid, peptide and protein;

D is Q N, O, S, or a bond;

p is an integer from 1 to about 10;

 $R_1$  and  $R_4$ , independently of one another, are selected from the group consisting of H,  $-(CH_2)_p$ –D-Z, an alkyl group, an alkenyl group, an aryl group, an alkynyl group, and an alkyl ether group wherein any one of  $R_1$  and  $R_4$  are optionally substituted by one or more of an alcohol, an aminoalcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, an alkylthio, a urea, a thiourea, a guanidyl, or a carbamoyl group,  $R_1$ , and  $R_4$  may optionally be covalently linked with each other to form a cyclic moiety; and at least one of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from 8 to about 24 carbon atoms; and

R<sub>2</sub> and R<sub>5</sub>, independently of one another, are selected from the group consisting of H, an alkenyl group, an alkynyl group, an aryl group and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide; an ester, a mercaptan, a urea, a thiourea, a quanidyl and a carbamoyl group;

R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate;

X is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion;

m and n are 1:

i and j are integers selected from 2 to about 3; and k is an integer selected from 1 to about 3.

# 42. (Canceled)

43. (Previously presented) A compound having the formula:

44. (Previously presented) A compound having the formula:

45. (Canceled)

46. (Previously presented) A compound having the formula:

wherein

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

R<sub>2</sub> and R<sub>5</sub>, independently of one another, are selected from the group consisting of a, an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group;

X is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion;

m and n are1:

i and j are integers selected from about 2 to about 3; and k is an integer selected from 1 to about 3.

# 47. (Previously presented). The compound which is:

## 48. (Canceled)

# 49. (Previously presented) A compound having the formula:

$$NH_{2} \xrightarrow[H]{NH_{1}} (R_{2})_{m} \\ NH_{2} \xrightarrow[R_{1}]{(R_{2})_{m}} (R_{5})_{n} \xrightarrow[H]{NH_{2}} X_{a}^{-}$$

### wherein

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

 $R_2$  and  $R_5$ , independently of one another, are selected from the group consisting of an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group;

m and n are 1:

i and j are integers from about 2 to about 3;

k is an integer from 1 to about 3;

 $L_1$  and  $L_2$ , independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of CH<sub>2</sub>, O, S and NH.

# 50. (Previously presented) The compound which is:

# 51. (Previously presented) A compound having the formula:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 52. (Previously presented) The compound as claimed in claim 51, wherein  $R_7$  and  $R_8$  are H.
- 53. (Previously presented) A compound having the formula:

54. (Previously presented) A compound having the formula:

wherein

X is a physiologically acceptable anion; and

a is the number of positive charges in the compound divided by the valence of the anion.

## 55. (Previously presented) A compound having the formula:

### wherein

Q is N:

X is a physiologically acceptable anion;

a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion;

 $R_1$  and  $R_4$ , independently of one another, are selected from the group consisting of H,  $-(CH_2)_p$ –D-Z, an alkyl group, an alkyl ether group, an alkenyl group, an aryl group, and an alkyl or alkyl ether group substituted by one or more of an alcohol, an aminoalcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, an alkylthio, a urea, a thiourea, a guanidyl, or a carbamoyl group,  $R_1$  and  $R_4$  may optionally be covalently linked with each other, to form a cyclic moiety; and at least one of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from 8 to about 24 carbon atoms;

R<sub>2</sub> and R<sub>5</sub>, independently of one another, are selected from the group consisting of H, an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamovl group:

Z is selected from the group consisting of amine, spermiyl, spermidyl, carboxyspermiyl, guanidyl, spermidinyl, putricinyl, pyridyl, piperidinyl, pyrrolidinyl, aminoacid, peptidyl, diaminoalkyl, and polyamine;

D is N, O, S, or a bond;

i and j are integers from about 2 to about 3;

k is an integer from 1 to about 3;

m, n, r and u are 1;

p is an integer from 1 to about 10;

 $L_1$  and  $L_2$ , independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of  $CH_2$ , O, S and NH.

56. (Previously presented) The compound as claimed in claim 55 wherein  $R_1$  and  $R_4$ , independently of one another, are straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl groups having from about 8 to about 24 carbon atoms

58. (Previously presented) A compound having the formula:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

59. (Previously presented) The compound as claimed in claim 58, wherein  $R_7$  and  $R_8$  are H.

61. (Previously presented) A compound having the formula:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 62. (Previously presented) The compound as claimed in claim 61, wherein  $R_7$  and  $R_8$  are H.
- 63. (Canceled)
- 64. (Previously presented) A compound having the formula:

### wherein

X is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion;

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms:

R<sub>2</sub> and R<sub>5</sub>, independently of one another, are selected from the group consisting of an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamovl group:

m and n are1:

i and j are integers from about 2 to about 3;

k is an integer from 1 to about 3;

 $L_1$  and  $L_2$ , independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of CH2, O, S and NH.

# 65. (Previously presented) The compound which is:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 67. (Previously presented) The compound as claimed in claim 66, wherein  $R_7$  and  $R_8$  are H.
- 68. (Previously presented) A compound having the formula:

wherein R7 and R8 are independently H or a carbohydrate.

- 69. (Previously presented) The compound as claimed in claim 68, wherein  $R_7$  and  $R_8$  are H.
- 70. (Canceled)

$$\sum_{L_1 - \frac{1}{N_1}}^{(R_2)_m} \left\{ (CH_2)_i - Y - (CH_2)_j \right\}_{k}^{(R_5)_n}$$

#### wherein

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

 $R_2$  and  $R_5$ , independently of one another, are selected from the group consisting of an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group;

m and n are 1:

i and j are integers from about 2 to about 3;

k is an integer from 1 to about 3;

 $L_1$  and  $L_2$  independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of CH<sub>2</sub>, O, S and NH.

# 72. (Previously presented) The compound which is:

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 74. (Previously presented) The compound according to claim 73, wherein  $R_7$  and  $R_8$  are H.
- 75. (Previously presented) A compound having the formula:

wherein R7 and R8 independently are H or a carbohydrate.

- 76. (Previously presented) The compound as claimed in claim 75, wherein  $R_7$  and  $R_8$  are H.
- 77. (Canceled)

# 78. (Currently amended) A compound having the formula:

wherein

X is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion:

each of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms;

 $R_2$  and  $R_5$  independently of one another, are selected from the group consisting of an alkenyl group, an aryl group, and an alkyl group optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group;

m and n are 1:

i and j are integers from about 2 to about 3;

k is an integer from 1 to about 3:

 $L_1$  and  $L_2$ , independently from one another, are an alkylene or an alkylene ether; and

Y is selected from the group consisting of CH2, O, S and NH.

# 79. (Previously presented) A compound having the formula:

$$\begin{picture}(20,10) \put(0,0){\line(0,0){$N$}} \put(0,0){\line(0,0){$N$$

$$\begin{picture}(20,10) \put(0,0){\line(1,0){$N$}} \put(0,0){\line(1,0){$N$$

wherein R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 81. (Previously presented) The compound as claimed in claim 80, wherein  $R_7$  and  $R_8$  are H.
- 82. (Previously presented) A compound having the formula:

wherein  $R_7$  and  $R_8$  are independently H or a carbohydrate.

83. (Previously presented) The compound as claimed in claim 82, wherein  $\mbox{R}_7$  and  $\mbox{R}_8$  are H.

# 85. (Previously presented) A compound having the formula:

wherein

X is a physiologically acceptable anion;

a is the number of positive charges in the compound divided by the valence of the anion;

Y is selected from the group consisting of  $CH_2$ , an ether, a polyether, an amide, a polyamide, an ester, a sulfide, a urea, a thiourea, a guanidyl, a carbamoyl, a carbonate, a phosphate, a sulfate, a sulfoxide, an imine, a carbonyl, and a secondary amino group and wherein Y is optionally substituted by  $-X_1-L'-X_2-Z$  or -Z;

 $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H,  $-(CH_2)_0$ -D-Z, an alkyl group, an alkenyl group, an aryl

group, an alkynyl group, and an alkyl ether group wherein any one of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  are optionally substituted by one or more of an alcohol, an aminoalcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, an alkylthio, a urea, a thiourea, a guanidyl, or a carbamoyl group, and at least one of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from 6 to about 64 carbon atoms; and  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  may optionally be covalently linked with each other or with Y, to form a cyclic moiety:

Z is selected from the group consisting of amine, spermiyl, carboxyspermiyl, guanidyl, spermidinyl, putricinyl, diaminoalkyl, pyridyl, piperidinyl, pyrrolidinyl, polyamine, amino acid, peptide, and protein;

 $X_1$  and  $X_2$ , independently of one another, are selected from the group consisting of NH. O. S. alkylene, and arviene:

L' is selected from the group consisting of alkylene, alkenylene, alkynylene, arylene, alkylene ether, and polyether;

D is O, S, or a bond;

m and n are 1: and

i. i. k. I and p are integers from 1 to about 10.

- 86. (Previously presented) The compound as claimed in claim 85, wherein at least one of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms.
- 87. (Previously presented) The compound as claimed in claim 85, wherein the alkyl ether optionally substituted by one or more alcohol groups is a carbohydrate.
- 88. (Previously presented) The compound as claimed in claim 87, wherein the carbohydrate is selected from the group consisting of galactose, fructose, glucose, maltose, sucrose, cellobiose, lactose, mannose, glucopyranose, mannopyranose and galactopyranose.

- 89. (Previously presented) The compound as claimed in claim 85, wherein Y is selected from the group consisting of CH<sub>2</sub>, an ether, a polyether, an amide, a polyamide, an ester, a sulfide, a urea, a thiourea, a guanidyl, a carbamoyl, a carbonate, and a secondary amino group.
- 90. (Previously presented) The compound as claimed in claim 89, wherein at least one of  $R_1$  and  $R_4$  is a straight-chain, branched, or cyclic alkyl, alkenyl, alkynyl or aryl group having from about 8 to about 24 carbon atoms.
- 91. (Previously presented) The compound as claimed in claim 89, wherein the alkyl ether optionally substituted by one or more alcohol groups is a carbohydrate.
- 92. (Previously presented) The compound as claimed in claim 91, wherein the carbohydrate is selected from the group consisting of galactose, fructose, glucose, maltose, sucrose, cellobiose, lactose, mannose, glucopyranose, mannopyranose and galactopyranose.

# 93-100. (Canceled)

- 101. (Previously presented) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138.
- 102. (Previously presented) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one additional component selected from the group consisting of a cell, cells, a cell culture, a cell culture media, a neutral lipid, a nucleic acid, and a transfection enhancer.

### 103. (Canceled)

104. (Previously presented) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138.

105. (Canceled)

106. (Canceled)

107. (Previously presented) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one additional component selected from the group consisting of a cell, cells, a cell culture medium, a nucleic acid, a transfection, enhancer and instructions for transfecting a cell or cells.

108. (Previously presented) A method for introducing a polyanion into a cell or cells, said method comprising forming a lipid aggregate from a positively charged compound of any one of claims12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138, contacting the lipid aggregate with a polyanion to form a positively-charged polyanion-lipid aggregate complex and incubating the complex with a cell or cells.

109. (Previously presented) A method for introducing a biologically active substance into a cell, said method comprising forming a lipid aggregate of a compound of any one of claims 112, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and a biologically active substance and incubating the lipid aggregate with a cell or cell culture.

110. (Canceled)

111. (Previously presented) A compound which is:

 $\label{eq:normalizero} $N^1,N^4$-dialmitolyl-N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-diaminobutane; $N^1,N^4$-distearyl-N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-diaminobutane; $N^1,N^4$-dialminobutane; $N^1,N^2$-dimyristyl-N^1,N^2$-di-[2-hydroxy-3-(N-aminopropyl)]-diaminobutane; $N^1,N^2$-dialminobutane; $N^1,N^2$-dialminobutane; $N^1,N^2$-dialminobutane; $N^1,N^2$-dialminobyl-N^1,N^2$-di-[2-hydroxy-3-(N-aminopropyl)]-diaminoethane; $N^1,N^2$-dialminobyl-N^1,N^2$-di-[2-hydroxy-3-(N-aminopropyl)]-diaminoethane; $N^1,N^2$-dialminobyl-N^1,N^2$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^2$-dialminobyl-N^1,N^2$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^2$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^3$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^3$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^3$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^3$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^3$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^3$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^3$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^3$-dialminobyl-N^1,N^3$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-dimyristyl-N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-dimyristyl-N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-dimyristyl-N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jeffamine; $N^1,N^4$-di-[2-hydroxy-3-(N-aminopropyl)]-Jef$ 

- aminopropyl]-diaminobutane; N¹ N²-dinalmityl-N¹ N²-di-f2-hydroxy-3-(N-sperminecarboxamido)-
- N',N'-dipalmityl-N',N'-di-[2-hydroxy-3-(N-sperminecarboxamido)aminopropyl]-diaminobutane;
- $N^1, N^4\text{-dipalmitolyl-}N^1, N^4\text{-di-}[2-\text{hydroxy-}3-(N-\text{sperminecarboxamido})-$  aminopropyl]-diaminobutane;
- $N^1,N^4\text{-dilauryl-}N^1,N^4\text{-di-}[2\text{-hydroxy-}3\text{-}(N\text{-sperminecarboxamido})\text{-}$  aminopropyl]-diaminobutane;
- N<sup>1</sup>,N<sup>8</sup>-dimyristyl-N<sup>1</sup>,N<sup>8</sup>-di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyll-Jeffamine;
- N<sup>1</sup>,N<sup>8</sup>-dipalmityl-N<sup>1</sup>,N<sup>8</sup>-di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-Jeffamine;
- $\label{eq:N-N-N-dipalmitolyl-N-N-di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-Jeffamine;} \\$

N¹,N³-distearyl-N¹,N³-di-[2-hydroxy-3-(N-sperminecarboxamido)aminopropyl-Jeffamine:

 $\label{eq:N-dilauryl-N-dilauryl$ 

 $\label{eq:N4-N4-dioleyl-N1-N4-di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-Jeffamine;$ 

 $N^1,N^2\text{-}dimyristyl-N^1,N^2\text{-}di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-diaminoethane;} \\$ 

 $N^1,N^2$ -dipalmityl- $N^1,N^2$ -di-[2-hydroxy-3-(N-sperminecarboxamido)-aminopropyl]-diaminoethane;

 $N^1,N^2\text{-dipalmitolyl-}N^1,N^2\text{-di-}\{2\text{-hydroxy-3-}(N\text{-sperminecarboxamido})\text{-}$   $aminopropyl\}\text{-diaminoethane};$ 

 $\label{eq:N1N2-distearyl-N1N2-di-[2-hydroxy-3-(N-sperminecarboxamido)-} \\ aminopropyl]-diaminoethane; or$ 

 $N^1,\,N^2\text{-}dilauryl\text{-}N^1,N^2\text{-}di-[2\text{-}hydroxy\text{-}3\text{-}(N\text{-}sperminecarboxamido)\text{-}} aminopropyl]\text{-}diaminoethane.$ 

# 112. (Previously presented) A compound which is:

- 113.-116. (Canceled)
- 117. (Previously presented) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one additional lipid aggregating compound.
- 118. (Previously presented) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one additional lipid aggregating compound selected from DOPE. DOPC or cholesterol.
- 119. (Previously presented) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one neutral lipid or at least one other cationic lipid.
- 120. (Previously presented) A composition comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one cationic lipid selected from the group consisting of DOSPA. DOTMA. DMRIE. DOTAP. DOGS and TM-TPS.
- 121. (Previously presented) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138.
- 122. (Currently amended) A kit comprising one or more compounds of any one of elaims 1 claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one additional lipid aggregating forming compound.

- 123. (Previously presented) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one additional lipid aggregating forming compound selected from DOPE. DOPC or cholesterol.
- 124. (Previously presented) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one neutral lipid or at least one other cationic lipid.
- 125. (Previously presented) A kit comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one other cationic lipid selected from the group consisting of DOSPA, DOTMA, DMRIE, DOTAP, DOGS and TM-TPS.
- 126. (Previously presented) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one additional lipid aggregating forming compound.
- 127. (Previously presented) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one additional lipid aggregating forming compound selected from DOPE, DOPC or cholesterol.

- 128. (Previously presented) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one neutral lipid or at least one other cationic lipid.
- 129. (Previously presented) A lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, or 138 and at least one other cationic lipid selected from the group consisting of DOSPA, DOTMA, DMRIE, DOTAP, DOGS and TM-TPS.
- 130. Canceled
- 131. Canceled
- 132. Canceled
- 133. (Previously presented) A kit comprising a lipid aggregate comprising one or more compounds of any one of claims 12, 16, 21, 29, 32, 33, 35, 38, 41, 46, 49, 55, 64, 71, 78, 85, and 138 and at least one neutral lipid or at least one other cationic lipid.
- 134. Canceled
- 135. (Previously presented) The compound of claim 12 wherein  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H, and an alkyl group and at least two of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , are straight-chain alkyl groups having from 8 to 24 carbon atoms attached to each N.

136. (Previously amended) The compound of claim 135 wherein at least two of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , are straight-chain alkyl groups having 14 or 16 carbon atoms attached to each N.

- 137. (Canceled)
- 138. (Previously presented) A compound having the formula:

where:

Q is N:

L is a bivalent organic radical covalently linking each Q;

r, s, u and y are1;

X- is a physiologically acceptable anion;

a is the number of anions which is equal to the number of positive charges in the compound divided by the valence of the anion;

 $R_1,\,R_3,\,R_4,$  and  $R_6,$  independently of one another, are selected from the group consisting of H, an alkyl group, an alkenyl group, an alkynyl group, and an aryl group, wherein any one of  $R_1,\,R_3,\,R_4,$  and  $R_6$  are optionally substituted by one or more of an alcohol, an amine, an amide, an ether, a polyether, a polyamide, an ester, a mercaptan, a urea, a thiourea, a guanidyl, or a carbamoyl group, and at least two of  $R_1,\,R_3,\,R_4,$  and  $R_6$  are straight-chain, branched, or cyclic alkyl, alkynyl, or alkenyl groups having from 8 to 24 carbon atoms attached to each N and  $R_1,\,R_3,\,R_4$  and  $R_6$  are optionally covalently linked with each other; and

R<sub>7</sub> and R<sub>8</sub> are independently H or a carbohydrate.

- 139. (Previously presented) The compound of claim 138 wherein  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H, an alkyl group, an alkenyl group, or an alkynyl group.
- 140. (Previously presented) The compound of claim 138 wherein  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$ , independently of one another, are selected from the group consisting of H, and an alkyl group.
- 141. (Previously presented) The compound of claim 138 wherein  $R_7$  and  $R_8$  are H.
- 142 (Previously presented) The compound of claim 138 wherein two of  $R_1$ ,  $R_3$ ,  $R_4$ , and  $R_6$  are alkyl groups having 14 or 16 carbons.

#### REMARKS

Claims 10, 12-14, 16-19, 21-36, 38, 40, 41, 43, 44, 46, 47, 49-62, 64-69, 71-76, 78-92, 101, 102, 104, 107-109, 111, 112, 117-129, 133, 135, and 138-142 are in this case. Claims 16, 41 and 122 have been amended to correct clerical errors.

All of claims 10, 12-14, 16-19, 21-36, 38, 40, 41, 43, 44, 46, 47, 49-62, 64-69, 71-76, 78-92, 101, 102, 104, 107-109, 111, 112, 117-129, 133, 135, and 138-142 are objected to because the previous amendment faxed to the Patent Office on February 25, 2005 was at least in part illegible. Applicants believe that the previously filed amendment was entered and that all that is required to obviate the objection is a legible copy of the amendment that was filed.

Attached hereto as Appendix A is a copy of the Amendment and Response filed by FAX on February 25, 2005. The copy is identical in subject matter to the amendment faxed, however, the font size of letters and numerals in chemical formulas in the listing of claims has been increased or the size of the entire chemical formula has been increased to improve legibility of subscripts and other notation in the formulas. No new matter has been added to the Response.

#### Claim Amendments

Claims 16, 41 and 122 have been amended to correct clerical error.

Claim 16 has been amended to replace the numeral "1" with the letter "I" which is consistent with the formula of the claim.

Claim 41 has been amended to replace the variable "Q" with the definition of that variable which is "N, O, S." The phrase "D is Q or a bond" was introduced into claim 41 by amendment filed November 21, 2003. Claim 41 had been previously amended to depend from claim 1 where Q is defined as "N, O or S." Thus, we have inserted the definition of Q from original claim 1 into claim 41.

Claim 122 has been amended to delete a redundant phrase "claims 1."

These amendments represent the correction of obvious typographic or clerical errors and do not add new matter to the specification.

## The Objections to the Claims

All of the pending claims were objected to because of the partial illegibility of the previously filed response. Applicants have provided a legible copy of the previously filed response herewith.

Additionally, the Examiner noted informalities in claims 16 and 41. these informalities (typographic and clerical errors) have been corrected by the amendment presented in this response.

It is believed that the claim amendments and the submission of the fully legible copy of the previous response obviate this objection.

All formal matters having been corrected. All of the claims remaining in this case are believed to be allowable as was indicated by the Examiner. If any additional concerns arise, the undersigned respectfully requests a telephone call from the Examiner to expedite processing of the application to issue.

# Information Disclosure Statements

The Examiner requested Applicants assistance in reviewing the Information Disclosure Statements that had been filed and the copies of 1449 forms that had been initialed by the Examiner as considered. The undersigned has reviewed her records and the image file wrapper of the PAIR system. The undersigned cannot find initialed copies of the 1449 forms submitted in the initial Information Disclosure Statement filed in this case on March 9, 2000. Attached hereto as Appendix B is a copy of the IDS submitted to the Patent Office on March 9, 2000 containing 5 pages of 1449 forms which listed 51 references.

Also submitted is a copy of the postcard receipt date stamped by the US Patent Office indicating receipt of the IDS and the 51 references submitted. Applicant respectfully requests copies of initialed 1449 forms indicating that these references have been considered.

# Conclusion

This amendment is believed to place all of the claims in condition for allowance and passage to issuance is respectfully requested. It is believed that no fees are due with this submission. If this is incorrect, please deduct any required fees that may be due from deposit account 07-1969. It is believed that no Petition for Extension of Time is needed to make this submission timely filed. If this is incorrect please deduct the required petition fees from deposit account 07/1969.

Réspectfully submitted,

Sally A. Sullivan

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